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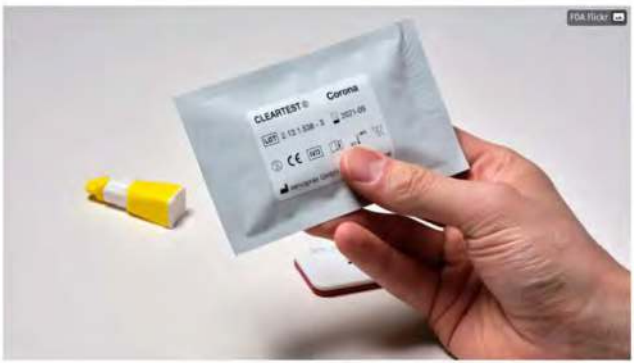


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# AACC says lab experts can fill gaps in FDA regulation by validating COVID-19 antibody tests

May 1, 2020


Now that diagnostic companies can sell COVID-19 antibody tests without U.S. Food and Drug Administration (FDA) authorization, healthcare teams should work closely with clinical laboratory experts to ensure that these tests are thoroughly validated and used appropriately, recommends the American Association for Clinical Chemistry (AACC) in



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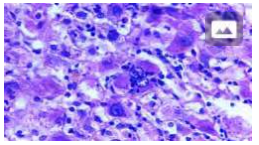

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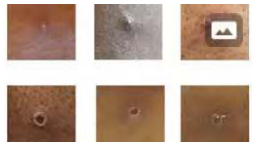

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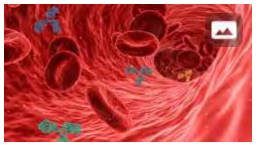

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a new opinion piece in its *Clinical Chemistry* journal. They further emphasize that this is critical to minimizing the risk of inaccurate results


from these tests, which could have potentially life-threatening consequences.

After it became clear that FDA's regulations were hampering COVID-19 testing, the agency relaxed its rules to the point that commercial diagnostic manufacturers can now sell COVID-19 antibody tests without FDA authorization. This change has allowed a flood of coronavirus antibody tests to hit the market, with more than 100 diagnostic companies offering or planning to offer these tests.

The surge in availability of these tests has also led to rising hopes that these antibody tests could help to reopen the country. This is because antibody tests are essential to population screening efforts that aim to determine the full extent of the COVID-19 outbreak, which government officials need to know in order to decide when and how to safely ease social distancing measures. However, worrying reports have emerged that many of these antibody tests give inaccurate results, and that some healthcare institutions are inappropriately using these tests to try to diagnose COVID-19 or to determine who is immune to the virus. These issues could lead to consequences such as people getting exposed to

issues could lead to consequences such as people getting exposed to COVID-19 because they mistakenly believe they are immune—and in a worst-case scenario, these problems could even potentially mislead government officials to lift stay-at-home orders prematurely.

To mitigate these risks, Drs. Christopher W. Farnsworth and Neil W. Anderson—lab experts from the Washington University School of Medicine in St. Louis—emphasize that it is up to the clinical laboratory community to fill the vacuum left by FDA and thoroughly examine the performance of antibody tests before they are used. The authors then go on to lay out recommendations for labs to follow when validating these tests. For example, labs should account for how widespread COVID-19 is in their area when designing test validation studies, since disease prevalence actually affects antibody test performance. Farnsworth and Anderson also recommend that labs use specimens from different sources to determine the likelihood that a test will give an inaccurate result. These sources should include symptomatic patients who have tested negative for COVID-19 using standard PCR tests for the virus, as well as patients who have tested positive for the milder coronaviruses that were already common in the U.S. prior to the COVID-19 outbreak.

In addition to validating COVID-19 antibody tests, Farnsworth and Anderson urge labs to communicate with healthcare providers about the

scenarios in which these tests should and should not be used. For example, antibody tests should not be used for COVID-19 diagnosis. As the authors observed, the median time from onset of symptoms to

patient presentation at their hospital is 3 days, but the most accurate COVID-19 antibody tests can't detect antibodies until 7-14 days after symptom onset. The authors also point out that antibody tests have limited utility as a backup for molecular COVID-19 tests. At their hospital, only about 1% of symptomatic, PCR-negative patients went on to test positive for antibodies.

"In conclusion, while serological assays have generated much hype, there is a need for data to support their clinical utility," said Farnsworth and Anderson. "When not properly evaluated they have the potential to misdiagnose and misinform. It is also crucial for laboratories to rigorously validate assays to assure they are suitable for their ultimate use. Furthermore, as the general public becomes enamored with the promise of COVID-19 serological testing, it is the responsibility of laboratory professionals to remind everyone of the potential peril."

AACC has the report.

More COVID-19 coverage HERE.

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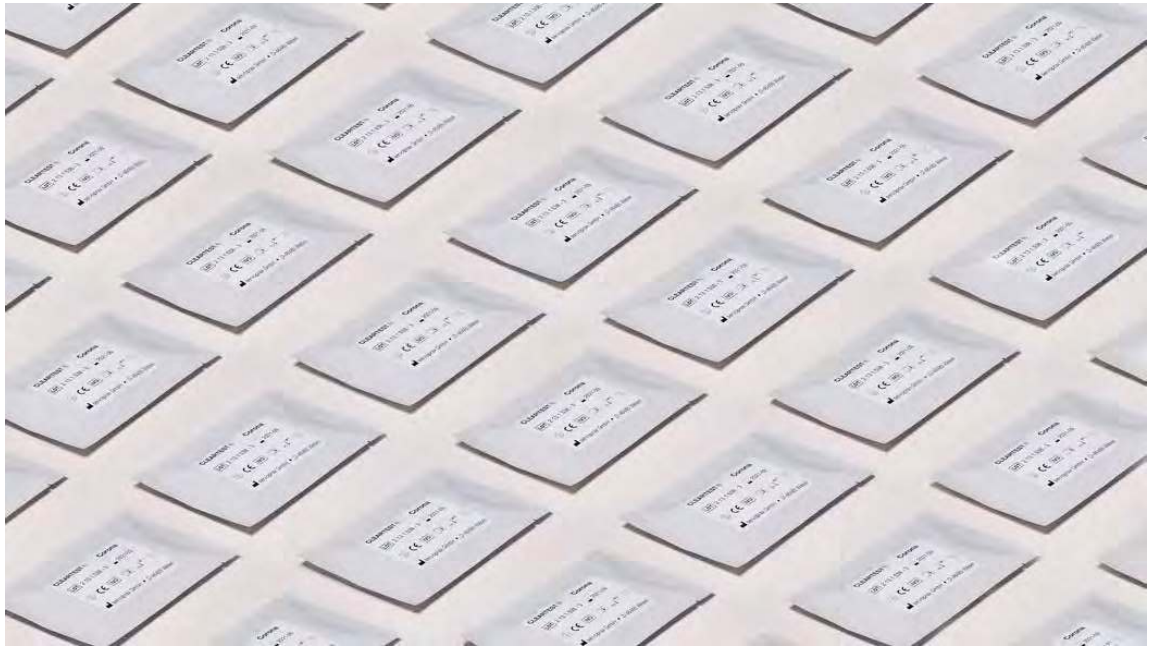
# FEMA to offer federal support to expand national testing capabilities

May 7, 2020



Under the Trump Administration's Guidelines for Opening America Up Again, states should meet at least five metrics before proceeding to a phased reopening, which includes demonstrating a downward trajectory of COVID-19 cases over a 14-day period as well as maintaining a robust system for testing health care workers, addresses the Federal Emergency



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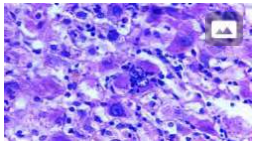

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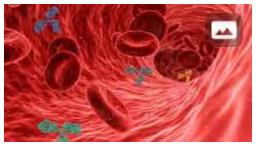

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Management Agency (FEMA). The Administration's Opening Up America Again Testing Overview and Testing Blueprint are designed to facilitate state development and implementation of the robust testing plans and rapid response programs described in the guidelines.

The Testing Blueprint sets forth the partnership between federal, state, local, and tribal governments, along with the private-sector and professional associations, all of which will play important roles in meeting the nation's testing needs.

The federal government provides strategic guidance on the best use of available technologies, approves new tests to expand capacity, shares best practices with states, and more.

As different localities have different needs, including the needs of low-income individuals, older adults, persons with disabilities, persons with limited English proficiency, and members of communities of color, states should each develop testing plans and rapid response programs that fit the needs of their communities and ensure equitable delivery of testing to individuals with civil rights protections.

States should make full use of the testing resources available to them, to include leveraging the full capacity available through commercial,

hospital and academic laboratories in addition to the capability available through public health laboratories.

To support the Testing Blueprint, FEMA, at the direction of the White House Coronavirus Task Force, is working to source and procure testing material – specifically, testing swabs and transport media. The FEMA-sourced material will be provided to states, territories and tribes for a limited duration to help increase testing capacity in support of their individualized reopening and testing plans. Once sourced and procured, the intent is to have this material shipped directly to the necessary location within each state, territory or tribe for their ultimate distribution. Each state, territory and tribal will develop its own distribution strategy to align with its testing plan and unique needs.

The Department of Health and Human Services (HHS) and FEMA lead a joint federal Laboratory Diagnostics Task Force focused on multiple paths to increase nationwide COVID-19 testing and support to governors nationwide to have the equipment, supplies, and testing resources needed to reopen safely and responsibly.

Key actions taken by this task force include:

· Supported states in identifying additional testing capacity and increasing use of testing platforms.

· Worked with diagnostic test developers and manufacturers to encourage rapid development of new technologies and scale up testing inventory.

· Distributed point-of-care analyzers and test kits to public health labs in all 50 states and U.S territories, as well as tribal communities through the Indian Health Service.

· Expanded reporting options for hospital diagnostic testing data through the HHS Protect system, which reduces burden on hospitals and ensures that the federal government has access to all in-house hospital laboratory testing data.

· Coordinated an interagency project team to include the White House, Food and Drug Administration, the National Institutes of Health, the Centers for Disease Control and Prevention, the Biomedical

Advanced Research and Development Authority and the Department of Defense to rapidly characterize the performance of serological diagnostic tests.

· Extensive serological antibody testing will provide the nation with more dense, broad-based data to look for prevalence of the COVID-19 antibody.

· Provided expert guidance to assist in rapid response to localized outbreaks in industries providing critical infrastructure.

· Collaborated with the Department of Energy labs and manufacturers to expand capacity for sample transportation, storage and preparation for optimal utilization of available tests and testing platforms.

· Expanded items supplied by the CDC's International Reagent Resource (IRR) to help registered public health labs access diagnostics supplies and reagents for COVID-19 testing free of charge, including:

· Consolidating ordering of testing supplies under the IRR to simplify the resource request process for states and territories and alleviate the burden on registered public health labs from needing to work with

separate suppliers for access to swabs, reagents and other critical diagnostic testing supplies.

· The Community-Based Testing Sites (CBTS) program, a short-term, high-impact initiative, was developed for states, local public health agencies, healthcare systems, and commercial partners as they work together to stop the spread of COVID-19 in their communities. This program focused initially on healthcare facility workers and first responders who are working around the clock to provide care and ensure the safety of Americans and now provides testing to asymptomatic and symptomatic individuals per the CDC testing criteria.

· 41 federal CBTS locations were approved with 151,950 samples tested as of May 5. CBTS focused initially on testing healthcare facility workers and first responders as they need to know their status to prevent infecting individuals in their care.

· The task force also prepared and distributed best practices for nasal self-swabbing to collect samples for COVID-19 testing, resulting in a reduction in the amount of required personal protective equipment.

· HHS and FEMA are working with states to assist them as they

transition from federal to state managed sites.

· Public-Private Partnership (CBTS 2.0) has expanded with private partners to include over 100 sites in 33 states. Through further expansion, the goal is to have over 200 sites in all 50 states, the District of Columbia and Puerto Rico with the ability to perform 15,000 tests per day.

· States, territories, tribes, and local governments may seek reimbursement for eligible expenses associated with coronavirus testing through FEMA's Public Assistance program. The Families First Coronavirus Response Act also appropriates $1 billion to reimburse providers for conducting coronavirus testing for the uninsured.

FEMA has the report.

More COVID-19 coverage HERE

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